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Nektar Therapeutics Presents Data for Rezpegaldesleukin (LY3471851) in Patients with Atopic Dermatitis and Psoriasis from Two Separate Clinical Studies at 2022 European Academy of Dermatology (EADV) Congress

SAN FRANCISCO, Sept. 7, 2022 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced data presentations from two Phase 1b, proof-of-concept studies of rezpegaldesleukin (also known as LY3471851 or NKTR-358) in patients with atopic dermatitis (AD) and plaque psoriasis at the 2022 European Academy of Dermatology and Venereology (EADV) Congress.

Rezpegaldesleukin is a novel, first-in-class selective regulatory T-cell (Treg) inducing IL-2 conjugate in development to treat autoimmune and inflammatory conditions. It is designed to target the immune system imbalance that results from increased levels of inflammatory T cells and reduced numbers and impaired function of regulatory T cells (Tregs). Decreased Treg numbers or impaired immunosuppressive function are known to contribute to the pathogenesis of multiple autoimmune and inflammatory diseases, including atopic dermatitis and psoriasis.[1]

Data are being presented at EADV from both a Phase 1b double-blind, randomized, placebo-controlled multiple-dose study evaluating the safety, tolerability, and pharmacokinetics of rezpegaldesleukin in patients with moderate-to-severe AD, as well as a Phase 1b double-blind, placebo-controlled study evaluating rezpegaldesleukin in patients with plaque psoriasis who are candidates for systemic therapy or phototherapy. Both studies were sponsored by Eli Lilly and Company.

"The results continue to demonstrate the potential of rezpegaldesleukin to emerge as a truly differentiated therapy for patients with serious inflammatory conditions," said Brian L. Kotzin, M.D., Chief Medical Officer of Nektar. "In atopic dermatitis, dose-dependent improvements in key efficacy measures were observed for an additional 36 weeks following the 12-week treatment period. These proof-of-concept data show rezpegaldesleukin's ability to stimulate Tregs to target an immune system imbalance resulting in an improvement of disease activity in patients."

Key details and takeaways from the presentations are as follows:

Abstract P1242: "*Efficacy and Safety of a Selective Regulatory T-Cell Inducing IL-2 Conjugate (LY3471851) in the Treatment of Atopic Dermatitis: A Phase 1 Randomised Study*"

- The IL-2 conjugate Treg stimulator, LY3471851, had a safety profile at the doses studied that supports further clinical development of LY3471851 in patients with AD
- A trend toward dose-dependent improvement was observed in EASI and vIGA-AD scores and EASI75, vIGA-AD (0,1), and Itch NRS ≥4-point improvement responder rates with LY3471851 vs. placebo through 12 weeks of treatment
- Improvements with LY3471851 24 µg/kg were sustained during follow-up to 48 weeks, up to 36 weeks following end of treatment
- Total Tregs and CD25^{bright} Tregs increased with LY3471851 vs. placebo up to Week 12

Abstract P1611: "*Efficacy and Safety of a Selective Regulatory T-Cell Inducing IL-2 Conjugate (LY3471851) in the Treatment of Psoriasis: A Phase 1 Randomised Study*"

- The IL-2 conjugate Treg stimulator, LY3471851, showed a safety profile consistent with previous studies[2]
- In patients treated with LY3471851:
    - Treg numbers increased
    - PASI, sPGA scores, and Itch NRS improved over the treatment period
    - PASI improvement was maintained after drug withdrawal up to Week 19

Details of the data presentations at EADV are listed below and are available on the scientific section of Nektar's website at http://www.nektar.com/science/scientific-posters-and-presentations.

Nektar entered into a strategic collaboration with Lilly in 2017 to develop and potentially commercialize rezpegaldesleukin (also known as NKTR-358). In partnership with Lilly, the Phase 2 program for rezpegaldesleukin includes the ongoing 280-patient Phase 2 study in lupus (NCT04433585), a second Phase 2 study planned to start in the first part of 2023 in atopic dermatitis and a third Phase 2 study being planned in a yet-to-be-announced autoimmune indication to potentially start in 2023.

About Rezpegaldesleukin

Autoimmune and inflammatory diseases cause the immune system to mistakenly attack and damage healthy cells in a person's body. A failure of the body's self-tolerance mechanisms enables the formation of the pathogenic T lymphocytes that conduct this attack. Rezpegaldesleukin is a potential first-in-class resolution therapeutic that may address this underlying immune system imbalance in people with many autoimmune and inflammatory conditions. It targets the interleukin-2 receptor complex in the body in order to stimulate proliferation of powerful inhibitory immune cells known as

regulatory T cells. By activating these cells, rezpegaldesleukin may act to bring the immune system back into balance.

Rezpegaldesleukin is being developed as a self-administered injection for a number of autoimmune and inflammatory diseases.

About Nektar Therapeutics

Nektar Therapeutics is a biopharmaceutical company with a robust, wholly owned R&D pipeline of investigational medicines in oncology, immunology, and inflammatory diseases as well as a portfolio of approved partnered medicines. Nektar is headquartered in San Francisco, California, with additional operations in Huntsville, Alabama. Further information about the company and its drug development programs and capabilities may be found online at http://www.nektar.com.

Nektar Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "continue," "may," "demonstrate," "potential," "designed," "emerge," "planned" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential of, and future development plans for NKTR-358 and our other drug candidates in research programs, the prospects and plans for our collaborations with other companies, and the timing of the initiation of clinical studies and the data readouts for our drug candidates. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include, among others: (i) our statements regarding the therapeutic potential of NKTR-358 and our other drug candidates are based on preclinical and clinical findings and observations and are subject to change as research and development continue; (ii) NKTR-358 and our other drug candidates are investigational agents and continued research and development for these drug candidates is subject to substantial risks, including negative safety and efficacy findings in ongoing clinical studies (notwithstanding positive findings in earlier preclinical and clinical studies); (iii) NKTR-358 and our other drug candidates are in various stages of clinical development and the risk of failure is high and can unexpectedly occur at any stage prior to regulatory approval; (iv) the timing of the commencement or end of clinical trials and the availability of clinical data may be delayed or unsuccessful due to challenges caused by the COVID-19 pandemic, regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, evolving regulatory requirements, clinical trial design, clinical outcomes, competitive factors, or delay or failure in ultimately obtaining regulatory approval in one or more important markets; (v) patents may not issue from our patent applications for our drug candidates, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (vi) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 5, 2022. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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1. Nussbaum L, et al. *Br J Dermatol*. 2021;184:14-24.
2. Fanton C, et al. J Transl Autoimmun. 2022;5:100152.

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